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Re: Patent Term Extension
Application for
U.S. Patent No. 5,951,974

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,951,974, which claims the human biological product PEG-Intron® (peginterferon-alfa-2b) and a method of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 435 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 435 days.

The period of extension has been calculated using the Food and Drug Administration (FDA) determination of the length of the regulatory review period published in the Federal Register of July 16, 2002 (67 Fed. Reg. 46680). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (877 - 777) + 394 \\ &= 444 \text{ days}\end{aligned}$$

Since the regulatory review period began July 30, 1997, before the patent issue date (September 14, 1999), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From July 30, 1997 to and including September 14, 1999 is 100 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year limit of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 444 days, would extend the patent from November 10, 2013 (35 U.S.C. § 154) to January 28, 2015, which is beyond the 14-year limit (the approval date is January 19, 2001, thus the 14 year limit is January 19, 2015). The period of extension is thus limited to January 19, 2015, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, November 10, 2013, to and including January 19, 2015, or 435 days.

U.S. Patent No. 5,951,974

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further limit the period of extension determined above.

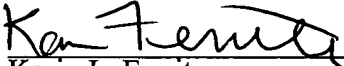
Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,951,974
Granted:	September 14, 1999
Original Expiration Date:	November 10, 2013
Applicant:	Carl W. Gilbert, et al.
Owner of Record:	ENZON, INC.
Title:	INTERFERON POLYMER CONJUGATES
Classification:	428/85.7
Product Trade Name:	PEG-Intron® (peginterferon-alfa-2b)
Term Extended:	435 days
Expiration of Extension:	January 19, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Mail Stop Patent Ext. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450.	By FAX:	(571) 273-7744
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Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.


Karin L. Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
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Rockville, MD 20857

Attention: Claudia Grillo

RE: PEG-Intron® (peginterferon-alfa-2b)
Docket No.: 01E-0366